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Application of: John Bruce Clayfield DAVIES

Confirmation No. 3991

Application No.: 10/628,014

Group Art Unit: 3731

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Examiner:

For: EXPANDABLE BONE NAILS

Attorney Docket No.: 85170-4600

SUBMISSION OF CERTIFIED PRIORITY DOCUMENT

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Sir:


Applicants have claimed priority under 35 U.S.C. § 119 of Application No. GB 0102141.9 filed January 27, 2001 in Great Britain. In support of this claim, a certified copy of said application is submitted herewith.

No fee or certification is believed to be due for this submission. Should any fees be required, however, please charge such fees to Winston & Strawn LLP Deposit Account No. 50-1814.

Respectfully submitted,

Date: _____

1/30/04


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1. Your reference DM/KG/P11275GB 29JAN01 E601317-10 000239
_P01/7700 0.00-0102141.9

2. Patent application number 0102141.9 27 JAN 2001
(The Patent Office will fill in this part)

3. Full name, address and postcode of the or of each applicant (underline all surnames) Dr John Bruce Clayfield Davies
1 Mansfield Court
Livingston Village
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Patents ADP number (if you know it)

6150627001 ID

If the applicant is a corporate body, give the country/state of its incorporation

4. Title of the invention Improvements in or Relating to
Expandable Bone Nails

5. Name of your agent (if you have one) Cruikshank & Fairweather

"Address for service" in the United Kingdom to which all correspondence should be sent (including the postcode) 19 Royal Exchange Square
Glasgow
G1 3AE

Patents ADP number (if you know it) 547002

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and (if you know it) the or each application number	Country	Priority application number (if you know it)	Date of filing (day / month / year)
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7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application	Number of earlier application	Date of filing (day / month / year)
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11. I/We request the grant of a patent on the basis of this application.

Signature

Date

Cruikshank & Fairweather

26.01.2001

12. Name and daytime telephone number of person to contact in the United Kingdom

Dr David Moreland

0141-221 5767

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IMPROVEMENTS IN OR RELATING TO EXPANDABLE BONE NAILS

The present invention relates to bone nails for positioning fractured bone portions relative to one another, and in particular, though not exclusively, to bone nails including expandable sections to laterally engage a cavity of each bone portion.

It is known that fractured bone portions can be united by the insertion of one or more bone nails (often known as intramedullary bone portion securing devices) which remain in place until the fracture is healed, and then are preferably removed though they may alternatively be renewed replaced or remain in-situ if required. Current bone nails typically have a diameter selected to provide sufficient strength to the nail while remaining narrow enough to seek to limit the size of the aperture through which the bone nail is inserted; in other words the amount of bone or diameter of marrow canal which has to be removed to insert the nail. Once in position one or more sections of the nail expand to increase the diameter of the nail over each relevant section. The expanded section(s) laterally engage the wall of the bone cavity (marrow canal) to fix the nail in position. Before the nail is removed the expanded section(s) are retracted to their original diameter to aid extraction.

Intramedullary devices as referred to above may conveniently be used in the setting of bone fractures, being particularly useful in the case of long bones for example, a femur, humerus, radius or ulna. Such sites

entail difficulties where the bone is required to be held in place, since these bones are usually surrounded by a considerable thickness of muscle, which spaces a rigid support of plaster of Paris from the bone by a distance which is too great to ensure that the bone is accurately aligned and firmly held. Moreover, when the arm or leg is in use, there may be rotary movement of the limb which could result in relative rotary movement between sleeve portions of the device.

Further, it is not uncommon for there to be more than one site of fracture in a bone, and particularly a long bone. Moreover, the fracture may involve splintering or fragmentation of the bone such that the overall length may be difficult to maintain whilst the bone is healing, resulting in a shortened limb.

An example of a bone nail is disclosed in US Patent No 4,453,539 to Raftopoulos et al entitled "An expandable intramedullary nail for the fixation of bone fractures". At one end of a sleeve are arranged a plurality of circumferentially spaced rectangular (or circular) openings. On rotating a screw thread along the bore of the sleeve, rectangular (or spherical) elements protrude through the sleeve to engage the bone cavity. In order to deploy the elements, an arrangement of spring clips, camming members and a pin is required. The number of parts which must be assembled to make this bone nail results in a device which is complex to construct, and hence may suffer from mechanical failure where segments fail to

deploy or worse, cannot be retracted for extraction of the bone nail.

An improved bone nail is that disclosed in UK Patent No 2,268,068 to the present Applicant entitled "Devices having expansion means for securing end portions of tubular members" the content of which is included herein by reference. The disclosed device is suitable for use with a fracture of long bones, such as the humerus, femur, radius or ulna, and comprises a rod adapted to be received within an elongate cavity of the bone. The nail is provided with at least two expansion sections mounted in tandem to grip wall portions of the cavity at two locations, one on each side of the fracture site. The sections each provide a plurality of substantially rectangular slits formed in a sleeve surrounding the rod. An end surface of the sleeve abuts a flange on the rod. Tightening a nut on the rod therefore causes the slits to distort, i.e. supposedly expand outwardly. Additionally the sleeve is in the form of a number of sleeve portions which are secured together by lugs and receiving slots in each portion so as to avoid relative rotational movement between the sleeve portions and between these and the rod.

This device has an advantage that it has a simple construction. However it also has a number of disadvantages. For example, the distortion of the slits is not controlled so the expanding portions may collapse inwards rather than expanding outwards on tightening. Further, on release the sleeve portions can become

disengaged from one another as the compression force is removed causing retraction and removal to fail.

It is an object of at least one embodiment of the present invention to obviate or mitigate at least one of the aforementioned disadvantages of the prior art.

According to a first aspect of the present invention there is provided a bone portion securing device adapted to be received within a bone cavity, the device including at least one portion capable of being radially expanded under an applied force, wherein the at least one expansion portion includes at least one slot, the slot having at least one portion having a width greater than a width of a remainder of the at least one slot.

Preferably the at least one portion and the remainder of the slot are longitudinally displaced.

Preferably there are provided a plurality of expansion portions.

Preferably the/each expansion portion includes a plurality of elongate slots.

Preferably the at least one wider portion is provided at or near an end of the/each slot.

Advantageously the/each slot includes a first and second wider portions at first and second ends of the slot.

Preferably the remainder of the slot is substantially of a uniform width.

Preferably the remainder of the slot includes a first and second substantially parallel edges.

Preferably the wider portion(s) is/are at least part

circular in an elongate plane of the slot.

According to one embodiment of the present invention the device comprises;

5 at least two expansion modules, said expansion module(s) being of substantially cylindrical unitary construction including a plurality of substantially longitudinal portions which, in use, are substantially lateral to a bone wall and which bow elastically outward when a compressive force is applied axially to the
10 expansion module;

at least one compression coupling, said compression coupling including compressive attachment means to engage the expansion module(s) in a fixed position with respect to the compression coupling and being capable of transferring
15 a compressive force; and

at least one compression means, said compression means being arranged to transfer a force, such as a rotational force, applied to at least one portion of a surface of the compression means to a compressive force applied to the at
20 least one compression coupling.

Preferably the plurality of longitudinal portions are substantially equidistantly spaced around a circumference of the expansion module(s).

Preferably adjacent longitudinal portions are
25 separated from each other by an elongate slot (expansion apertures).

Additionally the/each elongate slot may have chamfered edges.

In longitudinal cross-section the/each slot may have one end substantially broader than the oppositely opposed end. Alternatively one or both ends may be rounded.

5 More preferably the cross-section of the/each lead slot is dumb-bell shaped having circular end portions and a rectangular mid section. In a preferred embodiment the end portions have a diameter which is substantially twice the width of the rectangular mid section.

10 The dumb-bell shape of the expansion aperture seeks to ensure that when a compressive force is applied to one or both ends of the slot in the longitudinal direction, the longitudinal portion(s) will bow outwards from the expansion module.

15 Additionally, the longitudinal portions may be shaped to encourage them to bow elastically outward when the compressive force is applied. The shape may provide at least one narrowed mid section. The mid section may comprise a substantially central section radially thinner than the end sections of the respective longitudinal portion. Alternatively, the longitudinal portions may be
20 loaded by having a stepped or curved surface profile.

Preferably the compressive attachment means of the compression coupling is in the form of a ratchet. More preferably the ratchet is self locking. The compressive
25 attachment means may engage barbs on an external surface of the expansion module(s).

Preferably also the attachment means includes at least two anti-rotation grooves. The anti-rotation grooves

engage a portion of an expansion module such that the expansion module cannot rotate with respect to the compression coupling. Additionally, anti-rotation grooves may be included in the expansion module.

5 In a preferred embodiment the combination of a self locking ratchet together with anti-rotation grooves ensures that the components of the device remain attached to each other when the nail is extracted.

10 Preferably the device also comprises a central connector or rod. The central connector may be a tie bar. The expansion modules and the compression couplings may be mounted alternately onto the central connector to make up the required length of the device. Compression couplings of varying lengths can be used to allow for a desired separation between expansion modules.

15 The central connector may comprise a screw-threaded surface for engaging the components of the device. Alternatively the central connector may include one or more surfaces to engage at least a portion of a component mounted thereon.

20 Preferably the device also comprises a nose cone, positioned at a the front of the central connector or at a first expansion module, the compression means preferably being attached at a rear of the central connector or at a final compression coupling.

25 Preferably the nose cone has a rounded front face to provide for ease of insertion of the device into a bone cavity.

The nose cone may be attached to the central connector.

Alternatively the nose cone may be formed integrally with the central connector. Further the nose cone may include a sleeve.

Preferably also the nose cone may include rigid attachment means to engage a first expansion module in a fixed position with respect to the nose cone and consequently the central connector. Preferably the rigid attachment means is in the form of a ratchet. More preferably the ratchet is self locking. The rigid attachment may engage barbs on the external surface of the first expansion module.

The compressive attachment means and the rigid attachment means differ in that the compressive attachment means provides attachment between an expansion module and a compression coupling which, together transmit a compressive force. In contrast the rigid attachment means provides attachment between a nose cone and the first expansion module which, when a compressive force is applied to the first expansion module via the compressive means intermediary expansion module(s) and compression coupling(s), the first expansion module bears against a surface of the nose cone or a surface of the sleeve which applies the required compressive force for the longitudinal position(s) of the expansion module(s) to bow elastically outward.

Preferably the expansion module is made of a stiffly

resilient plastics material. In a preferred embodiment the expansion module is made at least partly of, and preferably substantially of, titanium or optionally of a titanium alloy. Alternatively, the expansion module is made of ultra-high molecular weight polyethylene (UHMWPE). The compression coupling and the compression means may be made of a metal or metal alloy. In a preferred embodiment the compression coupling and the compression means are made of titanium alloy e.g. TiAl₆V₄.

According to a second aspect of the present invention there is provided an expansion module for use as a portion of a bone portion securing device adapted to be received within a bone cavity, the module being capable of being radially expanded under an applied force, wherein the at least one expansion portion includes at least one slot the slot having at least one portion having a width greater than a width of a remainder of the at least one slot.

According to one preferred embodiment of the present invention the expansion module is of substantially cylindrical unitary construction and includes a plurality of substantially longitudinal portions which, in use, are substantially lateral to the bone wall which bow elastically outward when a compressive force is applied.

Preferably the expansion module includes coupling means for coupling the expansion module to other components of a bone portion securing device. Preferably the coupling means comprise barbs positioned on a surface of the

expansion module such that the barbs engage in a ratchet fashion when forced against a surface of another component. The coupling means may be self locking.

5 More preferably the coupling means includes a portion of the expansion module which engages a portion of another component such that the expansion module and the component are held in a fixed relationship and cannot rotate with respect to each other. The portion of the expansion device may be one or more anti-rotation grooves where the
10 component may comprise engaging lugs to the grooves or complimentary anti-rotation grooves.

Preferably the expansion module is made from a stiffly resilient plastics material such that it can elastically bow under a compressive force and return to its original
15 shape when the compressive force is removed. In an embodiment the expansion module is made of titanium. In a further embodiment the expansion module is made from a polymer of low calcium stearate superpressed UHMWPE, with a tensile stress of 700N/mm^2 and a creep (over 1000 hours)
20 of $230/250\text{Nmm}^2$.

According to a third aspect of the present invention there is provided a bone portion securing device comprising a plurality of parts adjacent ends of adjacent parts including one-way interengaging locking means adapted to
25 allow engagement of the adjacent ends but to prevent disengagement thereof.

Preferably, the locking means comprise ratchet means formed on the adjacent ends.

Preferably the locking means engage one another by relative movement of the adjacent ends together.

Preferably the ratchet means comprise first and second toothed or barbed surfaces formed on an inner facing surface(s) of a first part and an outer facing surface(s) of a second part.

Advantageously the surfaces each provide a plurality of teeth or barbs.

Advantageously the surfaces are substantially planar and may be substantially parallel to a long axis of the part upon which it is formed.

Preferably there are further provided means for preventing relative rotation of the adjacent parts when assembled together.

The means to prevent relative rotation may comprise interengaging grooves and lugs carried on each of the adjacent parts.

An embodiment of the present invention will now be described by way of example with reference to the accompanying drawings in which:

Figures 1 (a), (b) and (c) show a side view, an end view and a side view to an enlarged scale of an expansion module for use in a bone portion securing device according to an embodiment of the present invention;

Figures 2 (a) to (e) show profiles of longitudinal portions of an expansion module according to embodiments of the present invention;

Figures 3 (a) to (e) show a side, a further side view, a front view, an end view and a side view to an enlarged scale of a compression coupling for use in a bone portion securing device according to the present invention;

Figures 4 (a) to (c) show a side view, a further side view and an end view of a compression nut for use in a bone portion securing device according to the present invention;

Figures 5 (a) and (b) show a cross-sectional perspective view and a cross-sectional view of a nose cone for use in a bone portion securing device according to the present invention;

Figures 6(a) and (b) show a perspective view and a side view of a first end (front) portion of a bone portion securing device according to the present invention;

Figures 7 (a) and (b) show a perspective view and a side view of a second end portion of a bone portion securing device according to the present invention;

Figure 8 shows a partial fragmentary perspective diagrammatic representation of an view of a bone portion securing device according to the present invention; and

Figure 9 shows a schematic side view of a bone portion securing device according to the present invention, in use, within a bone cavity (drawn in cross-section for clarity).

Reference is first made to Figure 1(a) of the drawings which depicts an embodiment of the present invention comprising expansion module, generally indicated by reference numeral 10. Expansion module 10 is fashioned from a single piece of tubular material, e.g. titanium. The material is selected so that it will bow under an applied compressive force without splitting, crushing or deforming. Arranged circumferentially around the expansion module 10 are six longitudinal portions 12 spaced equally apart. Between each longitudinal portion 12 is a slot in the form of an expansion aperture 14. Each expansion aperture 14 has a generally dumb-bell shape provided by forming, e.g. drilling two circular apertures 16 a, 16 b and a connecting rectangular aperture 18. The edges of the expansion apertures 14 are chamfered and the expansion apertures are drilled through the entire thickness of the wall of the expansion module 10. At each end 28a, 28b of the expansion module 10 as best illustrated in Figure 1(c), are provided locking means comprising a set of external locking barbs 20. The barbs 20 are formed by removing an angular section of material circumferentially from the surface of the expansion module 10. Alternatively the barbs 20 could be cast or moulded with or onto the module 10. The barbs 20 are of uniform heights. In addition two small sections of each barb 20 are removed in the longitudinal direction of the expansion module 10. These small sections are formed at directly opposite sides of the expansion module 10 to form anti-rotation grooves 22a, b as

shown in Figure 1(b). The purpose of the apertures 16 a, b, barbs 20 and anti-rotation grooves 22a, b will be described hereinafter.

Each longitudinal portion 12 in Figure 1 is shaped to match the dumb-bell shape of the expansion apertures 14. Figures 2(a) to (e) show alternative embodiments of longitudinal portion 12 which are loaded to ensure successful outward bowing of the longitudinal portions 12 when a force is applied. Figure 2(a) shows in radial profile a longitudinal portion 12a for an expansion module. A narrow central section 110 is weaker than wider end sections 112a, 112b so that when a compressive force is applied to ends 114a, 114b the longitudinal portion 12a will bow outwards in the direction of the arrow A causing the narrow section 110 to engage with bone.

The arrangement shown in Figure 2(b) will provide an enhanced outward bowing effect of the longitudinal portion 12b as the central section 110 is now partly bowed when the expansion module is inserted into the bone.

Figure 2(c) shows a longitudinal portion 12c again in radial profile along the longitudinal axis of the expansion module. An inner surface 116 is stepped to provide indented portions 116a-d. This weakened inner surface will deform on compression of the ends 114a,b causing the longitudinal portion 12c to expand outwards in the direction of arrow A.

In Figure 2(d) both surfaces have been stepped with indents 116a, b, c which are arranged to weaken the longitudinal portion 12d on compression causing expansion

in the direction of arrow A.

Figure 2(e) shows a further embodiment of a longitudinal portion 12e viewed from above the edges of the portion 12e are curved to provide two wide sections 118a,b and a narrow central section 110 as for Figure 2(a) and (b) on compression of the ends 114,b. The central section 110 is pushed out of the page in the direction of A.

Reference is now made to Figure 3(a) of the drawings which depicts a compression coupling, generally indicated by reference numeral 24. A first end 26a provides a receiving ratchet of dimensions to engage an end 28a, 28b of an expansion module 10, as shown in Figure 3(e). Inwardly opposed barbs 30 also include matching anti-rotation grooves 32a, 32b to the grooves 22a, 22b of the expansion module 10. The anti-rotation grooves 32a, 32b are shown in Figure 3(c). At a second end 26b, figures 3(b) and 3(d) is a transverse slot 34. The slot 34 provides for the engagement of the coupling 24 to a compression nut.

In a further embodiment of the present invention the coupling 24 has substantially identical ends both as described for the first end 26a above.

The coupling 24 may be constructed of $TiAl_6$, bio-compatible non-corrosive alloy, which is strong enough to transmit a compressive force. The length of the coupling 24 is dependent on the separation required between expansion modules 10.

A coupling means comprising a nut 36 is illustrated in

Figure 4. The nut 36 is conveniently made of the same material as the compression coupling 24. The nut 36 comprises a hex screw head 38 which can be turned by a spanner or socket set. Internal to the nut 36 is a screw-threaded bore 40 which extends the length of the nut 36. One end 42 of the nut 40 is configured to mate with the transverse slot 34 of the compression coupling 24 described above.

A further component of an intermedullary bone nail is shown in Figure 5 and is generally referred to as a nose cone 44. A central tie bar 48 is a screw threaded rod running the length of the bone nail. An end section 46 of the bar 48 is threaded at a smaller size and fits into the nose cone body 50 which is bored and tapped. On assembling the nose cone 44, the end section 46 is welded or otherwise fixed into the nose cone body 50 and a TIG welded chamber 52 is provided to give a rounded front face 54 to the nose cone 44. A circumferential portion 58 of the nose cone 44 is formed to receive an end 28 of an expansion module by the same arrangement as described for the first end 26a of the compression coupling 24. At a front end of the circumferential portion 58 are surfaces which represent the compression face 56 for the bone nail.

The construction of an embodiment of an intermedullary bone portion securing device 61 will now be described making reference to Figures 6, 7 and 8.

A first expansion module 10a is inserted over the tie bar 48 and the barbs 20 at a first end 28a of the expansion

module 10a engage the circumferential portion 58 of the nose cone 44 in a self locking ratchet mechanism.

In addition complimentary anti-rotation grooves 32a, 32b interlock to prevent rotational movement of the expansion module 10a with respect to the nose cone 44. The barbs 20 of the second end 28b of the expansion module 10a mate with a compression coupling 24 which is mounted on the tie bar 48. Mating is by the self locking ratchet mechanism 29 and anti-rotation grooves 32a, 32b described hereinbefore. A joint assembly of the front 60 of a bone portion securing device 61 is shown in Figure 6.

Depending on the separation required between the two sets of longitudinal portions on adjacent expansion modules 10, one or more compression couplings 24 are mounted on the tie bar 48. Alternatively a single compression coupling 24 of the desired length is used. Any number of expansion modules 10 may be mounted on the tie bar 48 and it is optional as to whether compression couplings 24 are inserted between each expansion module 10.

When the desired number of expansion modules 10 have been inserted onto the tie bar 48 an end joint assembly 62 is constructed as shown in Figure 7. Once the final expansion module 10b is mounted on the tie bar 48 the bone nail 61 is completed with a final compression coupling 24a and the compression nut 36. The end 42 of the compression nut 36 is slid into the transverse slot 34 of the compression coupling 24a. When engaged together the coupling 24a is mounted on the tie bar 48 and the nut 36 is

screwed onto the end of the tie bar 48 to hold all components of the bone nail 61 in place. The compressive coupling 24a is held to the final expansion module 10b by a self locking ratchet mechanism and anti-rotation grooves 32a, 32b as described before. An exploded view of a complete bone portion securing device 61 is illustrated in Figure 8.

Reference is now made to Figure 9 of the drawings which illustrates an intermedullary bone portion securing device, generally indicated by reference numeral 10a, in use within a fractured bone generally indicated by reference numeral 66. The bone 66 has been drawn in cross-section to allow for clarity of view of the device 10a. The device 10a is shown received in the narrow channel or cavity 68 of the bone 66, which in the present example is a mammalian humerus. The bone 66 is shown with a fracture at 70 which requires bone portions 72 and 74 to be re-united.

The surgeon or veterinary practitioner will have pre-drilled a bore 76 through the bone cavity 68 to receive the device 64. This bone will be drilled at the elbow. With the compression nut 36 in an untightened position with all the components mounted on the tie bar 48, the device 61 is pushed into the bone 76. The front face 54 of the device 64 is rounded to reduce friction and aid insertion. The device 64 is positioned so that an expansion module 10a, 10b lies on either side of the fracture 70. When the correct positioning is obtained the compression nut 36 is

tightened using a spanner or socket wrench. On tightening the nut 36 the components are forced against each other towards the nose cone 44. The front end 28a of the first expansion module 10a bears against the compression face 56 of the nose cone 44 and applies a compression force. This is shown and described with reference to Figure 5. The force is transmitted through the components.

When each expansion module 10a, 10b is subjected to the axial compressive force, the expansion apertures 14 begin to widen and the longitudinal portions 12 bow outwards elastically. As the force is increased the length of each expansion module 10a, b decreases and the effective diameter of each expansion module 10 a, 10b increases. The longitudinal portions 12 bow until they contact the bone cavity wall 76. The shape of the expansion apertures 14 ensure that the longitudinal portions 12 bow outwards from the tie bar 48 and central axis of the device 64. Once expanded, the device 61 is held in position by the contact between the cavity wall 78 and the longitudinal portions 12. The expansion modules 10a, 10b remain expanded as long as the compression nut 36 remains tightened.

Once the fracture 70 has healed or if the device 61 requires to be removed, the compression nut 36 is loosened by reversing the above procedure. This releases the compressive force and the expansion modules 10a, 10b lengthen as the longitudinal portions 12 disengage from the cavity wall 78 and return to their original positions. The device 61 is then extracted from the healed bone by pulling

the device 61 from the bone 76. The incorporation of anti-rotation grooves and ratchet fittings between the components of the device 61 seeks to ensure that the components do not become detached from the device 61 during the extraction process.

A principal advantage of the present invention is that it provides a modular self locking IC humeral nail. In particular the bone portion securing device is designed to be fail safe in that, under compression, an expansion module of the device will always expand outwards to contact the cavity walls. In addition the device is designed so that it will not come apart when extracted from a bone.

It will be appreciated by one skilled in the art that various modifications may be made to the embodiments described hereinbefore without departing from the scope of the invention.

In particular, it will be appreciated that there may well be gaps between bone edges at any of the fractures but this is in no way detrimental to the operation of the securing device of the invention. Such gaps will in any case tend to fill in as the bone heals.

It will also be appreciated that the use of a device according to the invention may be controlled to an appreciable degree by the manner in which the apertures of the expansion module is formed. The extent of the deformation brought about by the application of compressive force in a longitudinal direction can be controlled by selection from a number of variables, e.g. number of

apertures in each annular group, thickness of expansion module wall, choice of material for the expansion module, width and/or length of apertures, width of position intervening between the apertures and so on. Moreover, the deformation characteristics of the expansion modules may be selected to vary between two or more area of the bone, so that selection expansion, sequentially arranged if desired, can be achieved.

It will also be understood that the cross-section of the expansion modules, longitudinal portions and couplings, although described as above as being conveniently circular, may be oval, triangular or any convenient cross-section as desired.

In addition, as briefly referred to above, there is the facility now provided for adjustment of the device during the insertion thereof if required.

It is also possible to select the material of the expansion modules and couplings so that they are degradable in time and does not require to be removed once the bone has healed. The rod means may be withdrawn from the bone through the access point, e.g. the elbow, at which actuation of the expansion devices was brought about.



Figure 1

Figure 1

2/9

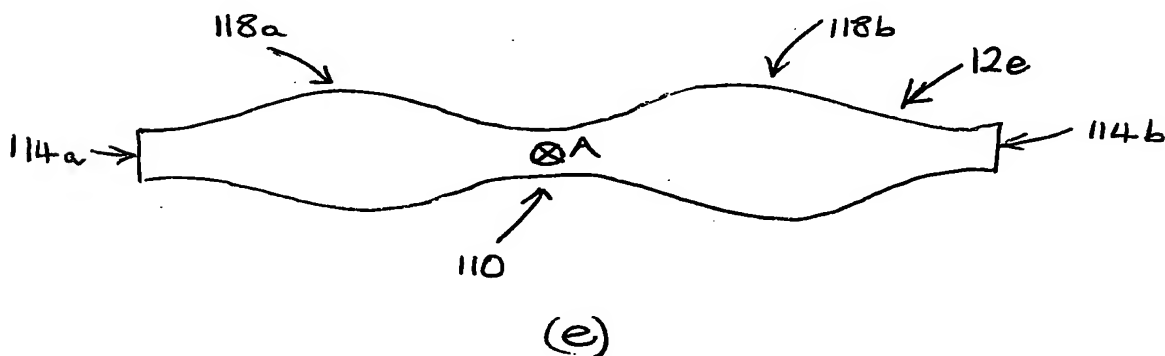
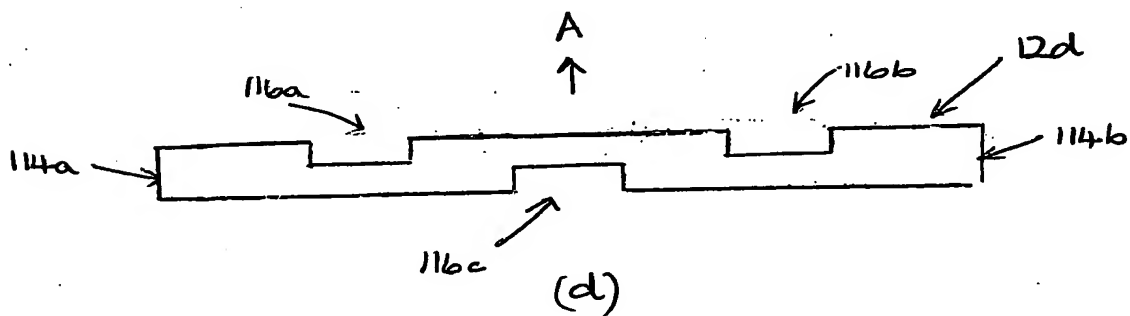
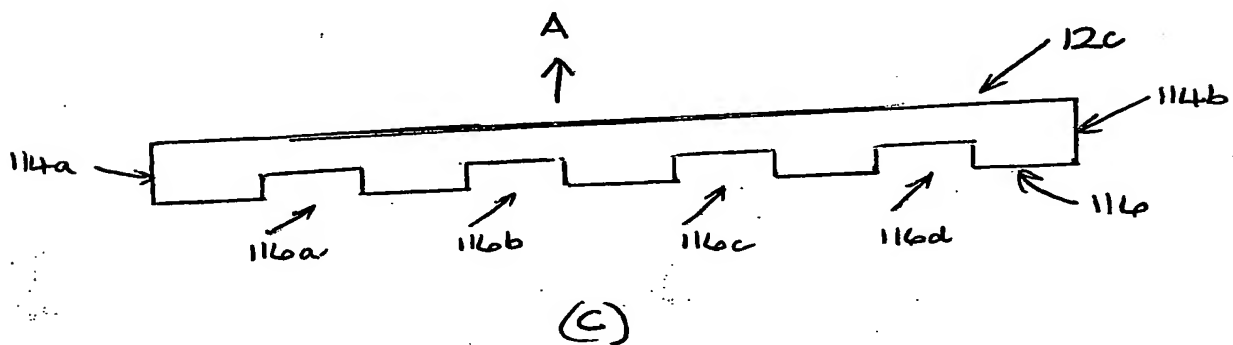
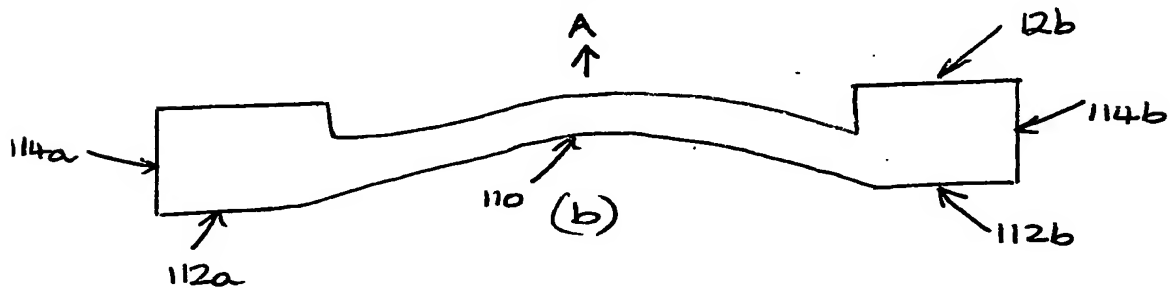
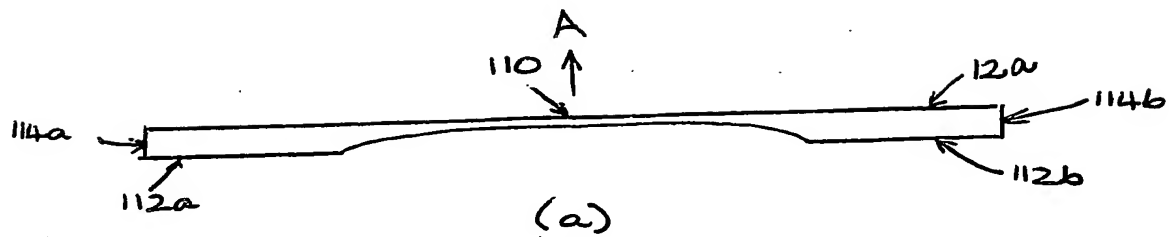
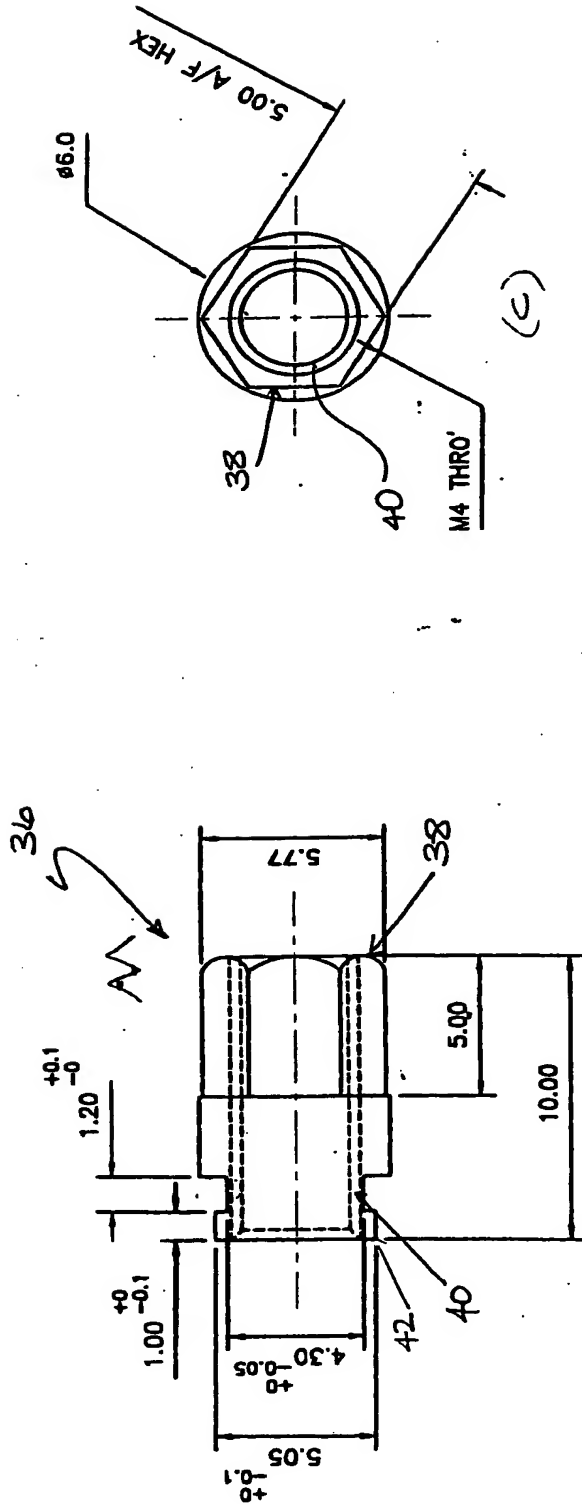


FIGURE 2

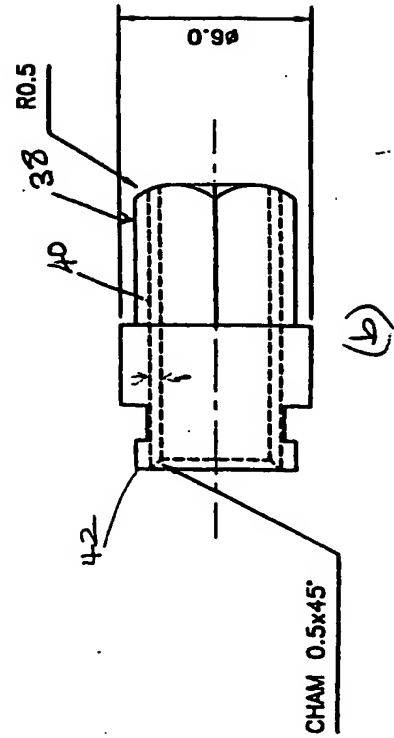


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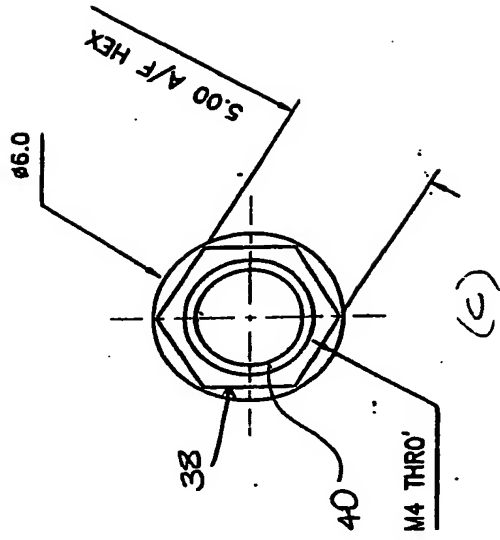
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(a)



(b)



(c)

FIGURE 4

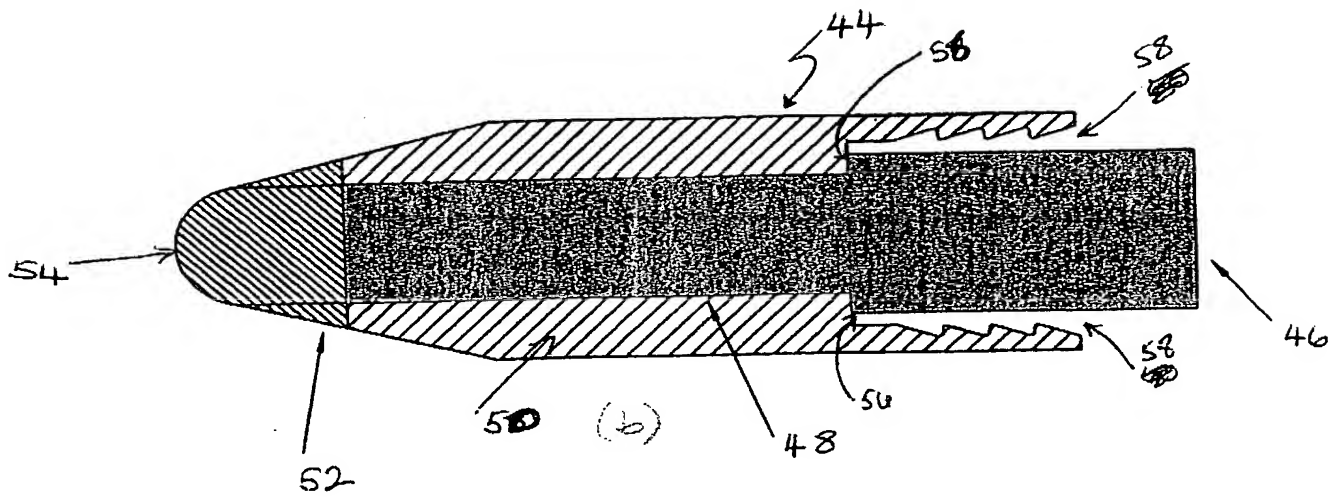
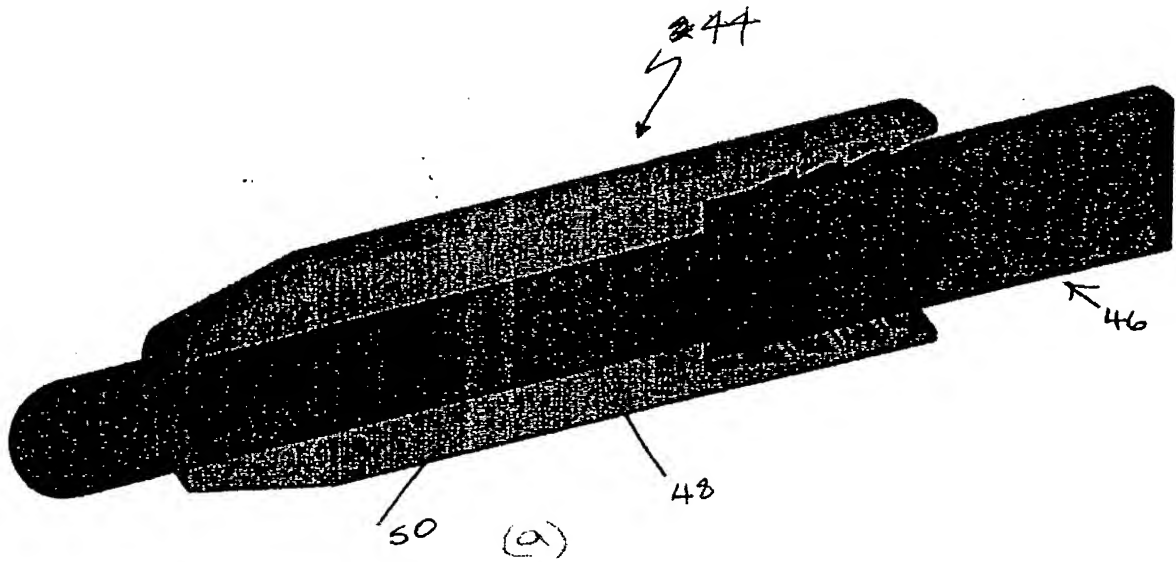


FIGURE 5

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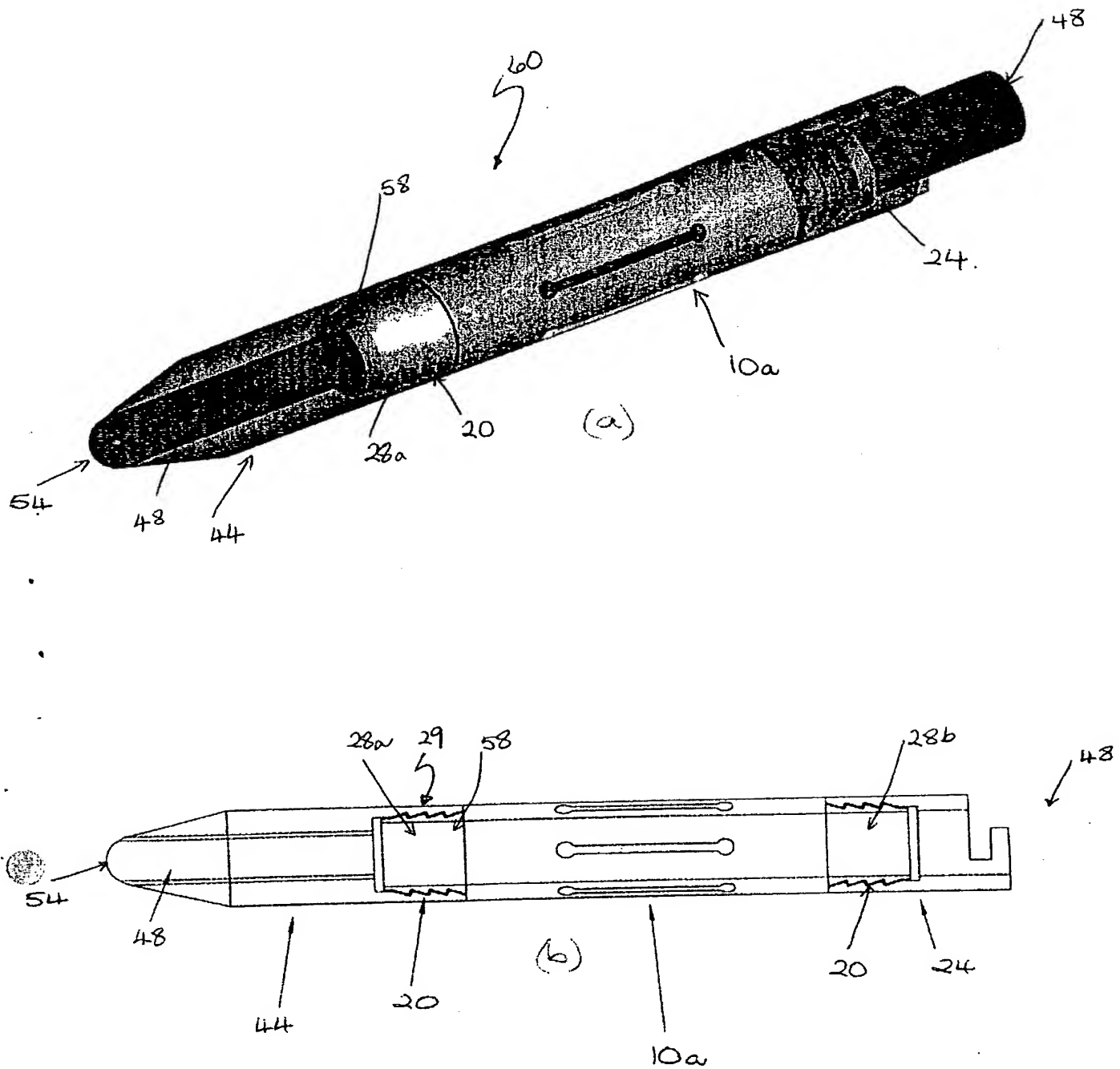


FIGURE 6

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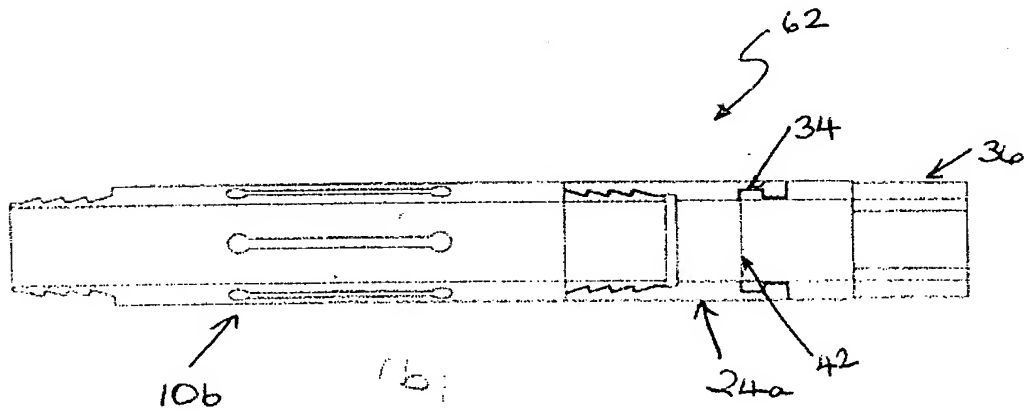
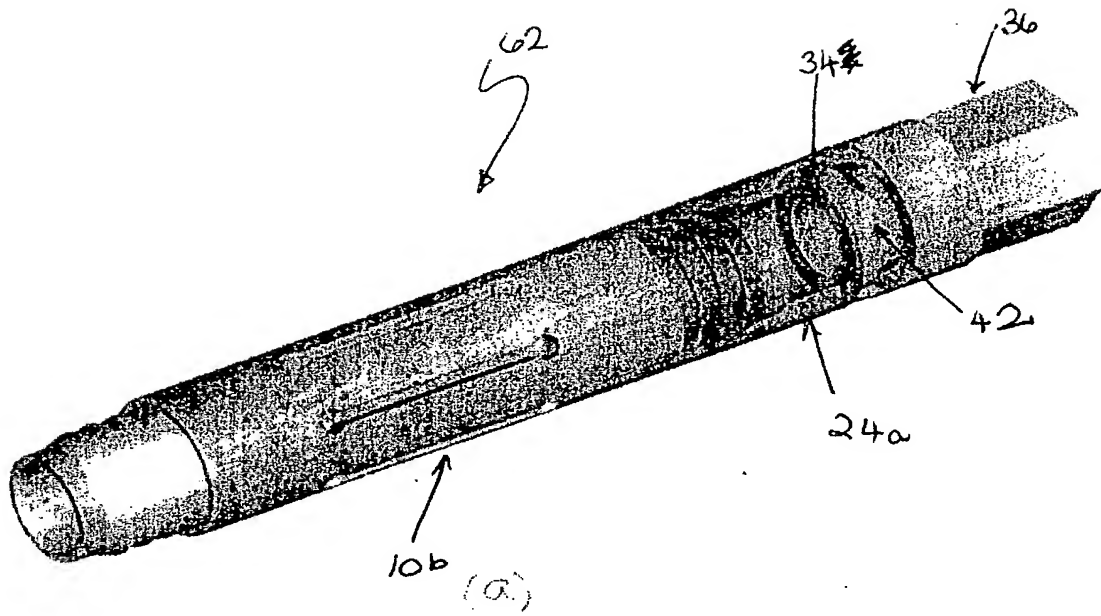


FIGURE 7

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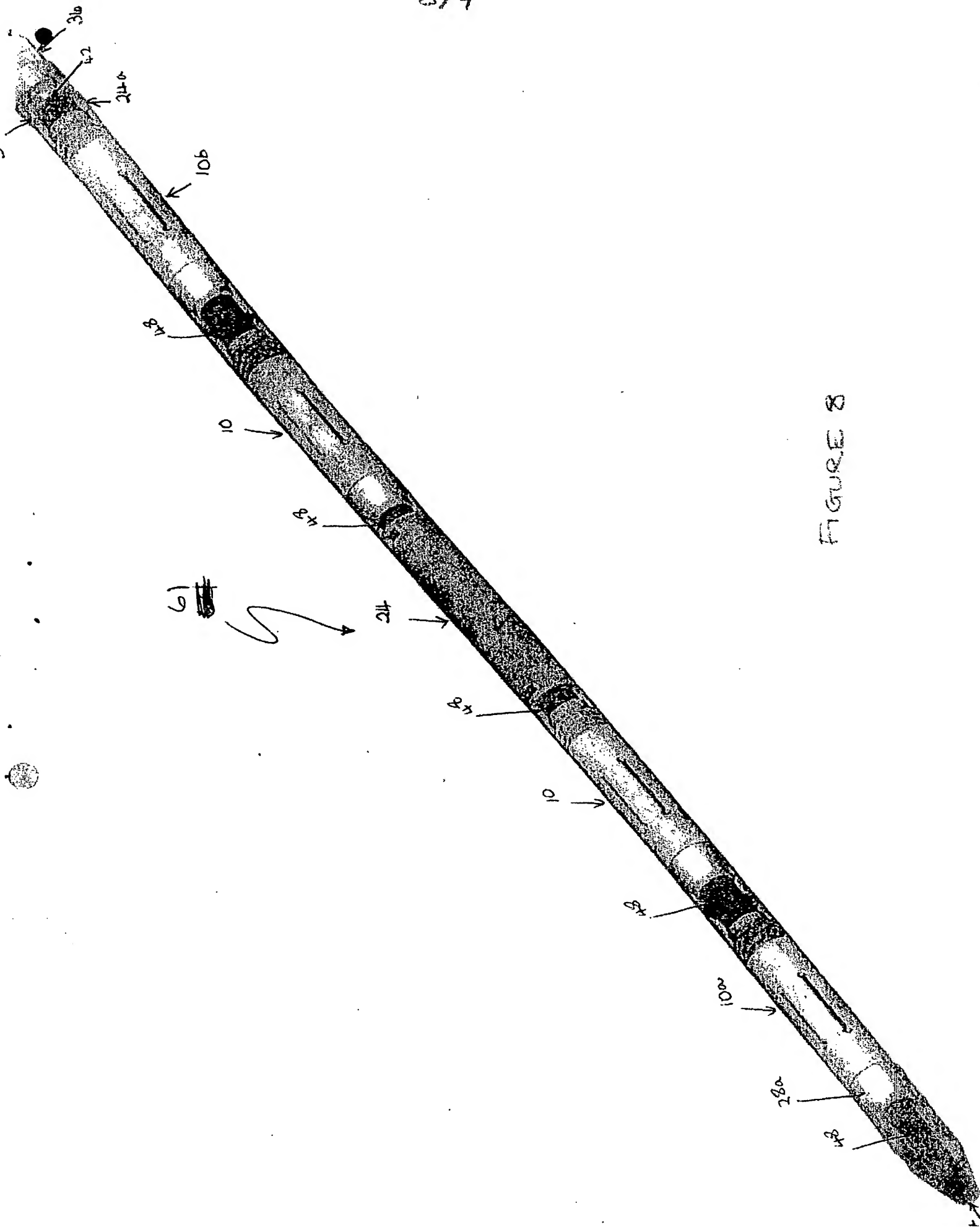


FIGURE 8

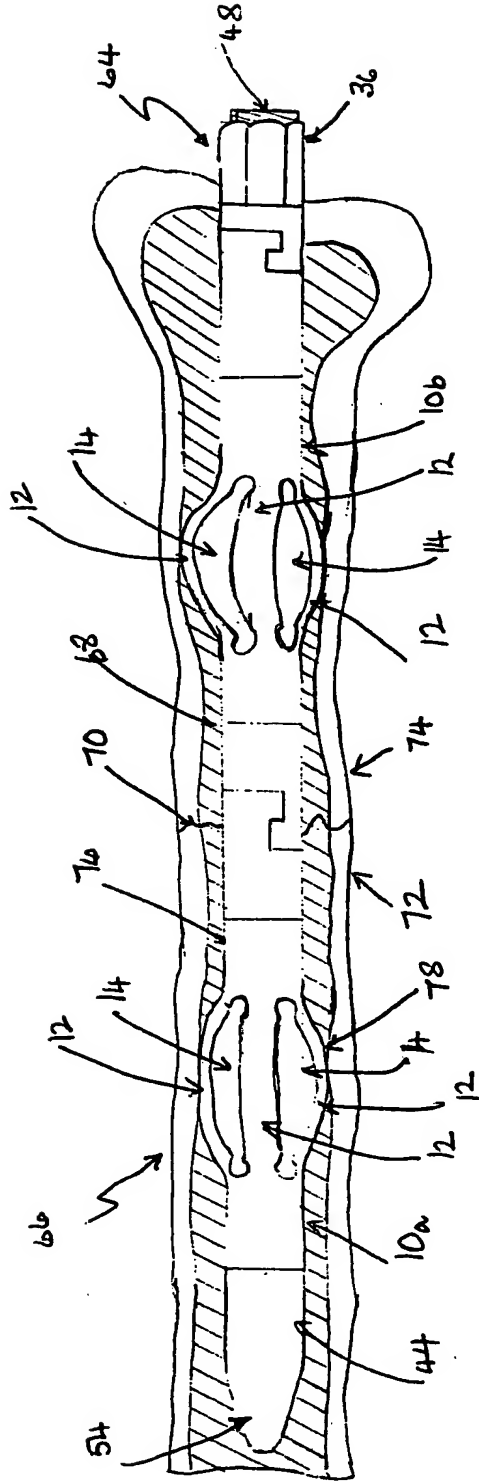


FIGURE 9



EXPRESS MAIL LIST

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The following items listed below are being filed herewith with the USPTO on **January 30, 2004**

Express Mail No. EV 346 810 440 US		
Attorney Docket No.	Appln. Serial No./ Patent No.	Items - Documents filed on January 30, 2004
81455-464	09/784,121	Response To Restriction (5 pages)
85170-4600	10/628,014	Petition For Extension of Time Under 37 CFR § 1.136(a); Response to Notice to File Missing Parts of Nonprovisional Application; Copy of Notice; Executed Inventor's Declaration and Power of Attorney; Submission of Certified Copy of Priority Document No. GB 0102141.9
103237-2	10/004,117	Petition For Extension of Time (1 page - in duplicate); Amendment (7 pages)

Please acknowledge receipt of these items as received by returning the enclosed postcards with the date of receipt of January 30, 2004

NY:833549.15

